Citation:

Gerhard GT, Ahmann A, Meeuws K, McMurry MP, Duell PB, Connor WE. Effects of a low-fat diet compared with those of a high-monounsaturated fat diet on body weight, plasma lipids and lipoprotiens, and glycemic control in type 2 diabetes. Am J Clin Nutr 2004;80(3):668-73.

PubMed ID: 15321807

Study Design:

Randomized Crossover study

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare 2 ad-libitum diets in type 2 diabetic patients--one high in monunsaturated fat and the other low in fat and high in fiber and complex carbohydrates--to ascertain which diet would lead to greater weight loss and greater improvements in dyslipidemia and glycemic control.

Inclusion Criteria:

- type 2 diabetes
- treated with oral glucose-lowering medications, diet, or both

Exclusion Criteria:

- insulin therapy within the previous 2 months
- HbA1c >12%
- medical conditions affecting plasma lipoprotein metabolism
- use of lipid-lowering medications within the previous 6 weeks
- proliferative retinopathy or nephropathy
- coronary events within the previous 6 months
- treatment with glucocorticosteroids
- fasting plasma cholesterol concentrations >300 mg/dl
- triglyceride concentrations > 700 mg/dl

Description of Study Protocol:

Recruitment: not specified

Design

- subjects were fed low-fat or high-monounsaturated fat metabolic diets in random order for 6

weeks, with the two diets separated by a 6-12-week washout period.
- both diets were offered at 25% above estimated energy requirements to allow for self-selection of quantity of food

Blinding used (if applicable): fat and carbohydrate content were changed by modifying recipes and portion sizes so that participants were blinded to diet so far as possible

Intervention (if applicable):

- low-fat diet: 20% fat, 65% CHO
- high-mono diet: 40% of energy from fat (25% of energy as monounsaturated fat), 45% CHO
- refined sugar made up 19% of calories for both diets
- the low-fat diet was higher in fiber and water
- both diets were low in saturated fat, but the low-fat diet had less saturated fat and cholesterol than the high-mono diet; this difference was intentional because it mirrors the composition of these types of diets in the "real world"

Statistical Analysis

- changes in body weight, plasma lipids, and lipoproteins, and glycemic variables were analyzed with the use of a two-factor analysis of variance model with repeated measures on time and diet.
- power calculations made (80% power and an alpha of 5%) for detecting a difference of 1% in HbA1c, a difference of 20% in plasma fructosamine, and a difference of 15% in fasting plasma glucose
- P values calculated for the main effects of time, diet, and the time x diet interaction.
- time x diet interaction tested for differential responses to the 2 different diets over time.

Data Collection Summary:

Timing of Measurements

- blood samples collected before and after each dietary period

Dependent Variables

- weight change, based on the differences between the mean weights on the first 3 days and on the last 3 days of the dietary phase
- fasting plasma lipids and lipoproteins using the Lipid Research Clinics program methods
- fasting plasma glucose using the glucose oxidase method
- HbA1c using HPLC on a Diamet analyzer
- plasma fructosamine using automated colorimetric assay
- glucose disposal and insulin sensititivty by hyperglycemic and euglycemic clamp studies

Independent Variables

- energy balance
- dietary intake
- all meals prepared by a metabolic kitchen staff at a clinical research center
- subjects consumed one meal at the research center and other meals, including weekend meals, were packaged for home consumption

Control Variables

Description of Actual Data Sample:

Initial N:11; 8 women and 3 men

Attrition (final N): 11

Age: 50.4±4.8

Ethnicity: not specified

Other relevant demographics:

- fasting plasma glucose, mg/dl 141±33
- HbA1c 6.8±1
- plasma fructosamine, mmol/dl 2.31±0.65

Anthropometrics

- weight, kg 101.0 ±17.8
- BMI 37.2±7.0

Location: United States

Summary of Results:

Weight

- The statistically significant time x diet interaction for the body weight changes indicated a differential response to the two diets, with weight loss being significantly greater on the low-fat diet.
- Weight loss was statistically significant only on the low-fat diet (-1.53±1.21 kg; P<0.001).

Changes in weight, plasma lipids, and plasma lipoprotein diets from initial to final values.

Variables	Low-fat diet	High-mono diet	p-value for time	p-value for diet	p-value for time x diet interaction
Body weight, kg	-1.53±1.23	-0.47±0.93	0.002	NS	0.045
total cholesterol, mg/dl	-9.6[2]	-10.2	0.011	NS	NS
LDL, mg/dlL	-10.2	-7.5	0.008	NS	NS
HDL, mg/dl	-7.1	-4.5	0.016	0.003	NS
VLDL, mg/dl	-10.5	-23.7	NS	NS	NS

triglycerides, mg/dl	-13.0	-23.2	NS	NS	NS

Nutrient Intake

- The subjects consumed 212 fewer kcal/d during the loow-fat diet than during the high-mono diet ($P < 0.02$).
- The subjects consumed significantly more ($P<0.05$) calories, fat, saturated fat, monounsaturated fat, and cholesterol while on the high-mono diet; they consumed significantly less ($P<0.05$) CHO and fiber while on that diet compared to when on the low-fat diet.

Glycemic control

- Plasma glucose, fructosamine, and HbA1c concentrations and glucose infusion rates during the clamp studies did not differ between the two diets; the changes were very small and unlikely to be of clinical importance.

Author Conclusion:

An ad-libitum , low-fat, high-fiber, high-complex-carbohydrate diet resulted in greater weight loss than did a high-mono diet, and the former did not increase plasma triacylglycerol concentrations from baseline or worsen glycemic control in patients with type 2 diabetes.

Reviewer Comments:

Power calculations made. Food provided by metabolic kitchen.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes